Leada Boot – Ambulatory Ankle / Foot Orthosis

INDICATIONS FOR USE:

- Plantar Flexion Contracture
- Internal/External Hip Rotation
- Heel Pressure Relief
- Initial Weight Bearing and Assisted Gait Training

FITTING INSTRUCTIONS:

NOTE: Semi Rigid Insert can be removed from liner and heat molded for plantar flexion contractures greater than 15° from neutral.

1. Open all hook and loop closures.
2. With the patient in a supine position, passively stretch the ankle/foot. Flex the knee to 45° or as close to 45 as comfort will allow.
3. Place the patient's foot in the AFO ensuring that the heel of the foot is at the apex of the AFO heel
4. While maintaining proper alignment of the foot in the AFO, bring the loop side of the foot portion of the liner over the top of the foot. Bring the opposite side of the liner over the top of the foot and secure the hook and loop closure, snug but not too tight.
5. Bring the loop side of the calf portion of the liner over the calf. Bring the opposite side of the liner over the calf and secure the hook and loop closure, snug but not too tight.
6. Bring the unsecured end of the anterior ankle strap over the top of the ankle aligning the strap with the black loop landing zone on the top of the foot. Continue taking the strap over the entire foot and loop the strap through the open slot at the bottom of the heel, then secure the strap back onto itself. The strap should be snug but not too tight. Adjust both ends of the strap if necessary. Attach the closure on the top of the liner over the strap
7. Check to ensure the heel is floating free and not touching the plastic insert.
8. Move the hip control bar if needed for internal or external hip rotation
9. Determine wearing schedule per therapy and/or physician's order
10. Use the device in a recumbent position only or for **assisted** weight bearing, transfer or gait training. ***This device is not an ambulating AFO***

IMPORTANT:

- Do not apply the device if there is significant skin redness that would come in contact with the device.
- Upon removal of the device, closely inspect skin integrity. If any redness is present, discontinue device use until skin integrity issues are resolved and the device is adjusted and/or wearing schedules adjusted accordingly

CONTRA-INDICATIONS:

- An ankle/foot with grade three plus edema
- An ankylosed ankle or and ankle/foot that is broken or dislocated

LAUNDRY INSTRUCTIONS:

1. Always remove soft cover from the frame before washing. Wipe frame with damp cloth or antibacterial wipe.
2. Close all hook and loop attachments on soft cover.
3. Hand or machine wash, gentle
4. Air or tumble dry low heat
5. No bleach or fabric softener
6. **DO NOT USE COMERCIAL WASHER OR DRYER**

WARNING: The product should be fit by trained personnel. The product is designed for single patient use only in order to avoid cross contamination. Any substitution or removal of the product's parts voids the manufacturer's warranty. OCSI Inc. will assume no liability if the above instructions are not followed.

REPORT A SERIOUS INCIDENT: The user and/or patient must report any serious incident that has occurred in relation to the device to the manufacture/distributor and the competent authority of the Member State in which the user and /or patient is established.

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EC REP

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